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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,527	06/18/2007	Allan L. Goldstein	2600-111	2965

6449 7590 10/26/2010

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
10/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/591,527	GOLDSTEIN, ALLAN L.	
	Examiner	Art Unit	
	ROY TELLER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 18-29* is/are pending in the application.

4a) Of the above claim(s) *9 and 19-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-14 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-14 and 18 in the reply filed on 9/29/10 is acknowledged. Applicant has elected the species, Thymosin beta 4, which reads on claims 1-8, 10-14 and 18.

Claims 9, and 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/29/10.

Claims 1-8, 10-14 and 18 are under examination.

Information Disclosure Statement

The information disclosure statement, received 9/11/07, is acknowledged. A signed copy is enclosed hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 10-14 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treatment for treating, or reducing extracelluar maxtrix build-up in a body tissue comprising administering thymosin beta 4, does not reasonably provide enablement for any preventing or inhibiting of extracellular matrix build-up in a body tissue comprising administering thymosin beta 4. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The invention is drawn to a method of treatment for treating, preventing, inhibiting or reducing extracelluar maxtrix build-up in a body tissue comprising administering thymosin beta 4. The breadth of the claims is undue with regard to the prevention or inhibition of extracelluar maxtrix build-up in a body tissue comprising administering thymosin beta 4.

The instant specification does not provide any guidance for the prevention or inhibition of extracelluar maxtrix build-up in a body tissue comprising administering thymosin beta 4. The instant specification discloses treatment and reduction of plaque build up, but not prevention or inhibition. See, for example, pages 10-11, examples 1-3.

Without such guidance one of ordinary skill in the art would be burdened with undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Goldstein et al (WO 03/020215).

The instant invention is drawn to a method of treatment for treating, preventing, inhibiting or reducing extracelluar maxtrix build-up in a body tissue (specifically coronary tissue) comprising administering thymosin beta 4.

Goldstein et al. discloses a method of treatment for promoting healing or preventing damage to coronary tissue comprising administering thymosin beta 4. See, for example, claims 1-5, 9-10, 12 and 15. Golstein et al. discloses administration may include intravenous, intrparitoneal, intramuscular or subcutaneous injections, or inhalation, transdermal or oral administration of the composition containing thymosin beta 4. See, for example, page 3, lines 29-31. Goldstein et al. discloses other proteins useful in the method of treatment, such proteins are LKKTET, TB9, TB10, TB11, TB12, TB13, TB14, Tb15, gelsolin, DBP, profiling, cofilin, adservertin, propomyosin, fincilin, depactin, vilin, fragmin, severin, and acumentin. See, for example, page 4, lines 7-34.

Therefore, the cited reference is deemed to anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (WO 03/020215).

Goldstein beneficially discloses a method of treatment for promoting healing or preventing damage to coronary tissue comprising administering thymosin beta 4. See entire document including, for example, Abstract.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the peptide agent in conjunction with the utilization of a stent or cardiac catheterization, or in combination with a plaque reducing agent or cholesterol reducing agent, based upon the overall beneficial teachings provided by Goldstein, as discussed above. If not expressly taught, the result-effective adjustment of conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0971. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
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/Christopher R. Tate/
Primary Examiner, Art Unit 1655